Section I. SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the Índigo Diffuser-Tip Fiberoptic with Temperature Sensing Option.

Submitter: Ethicon Endo-Surgery, Inc.
4545 Creek Road, Cincinnati, Oh 45242-2839
Telephone: 513-337-7987
Fax: 513- 337-2987

Contact Person: Jacquelyn A. Hughes, RAC

Device Name:

Trade Name:	Índigo Diffuser-Tip Fiberoptic with Temperature Sensing Option
Common Name:	Diode laser fiberoptic delivery system
Proprietary Name:	Índigo LaserOptic Treatment System®
Classification Name:	Accessory to Laser-powered surgical instrument

Date Prepared: December 8, 2000

Predicate Device:
The modified Índigo Diffuser-Tip Fiberoptic with Temperature Sensing Option is substantially equivalent to the current Índigo Diffuser-Tip Fiberoptic with Temperature Sensing Option cleared by FDA on December 23, 1997 (K990851).

Device Description:
The Índigo Diffuser-Tip Fiberoptic is a sterile, single-use, disposable fiberoptic which is 3 meters in length with a light-diffusing section at the distal tip. The device is designed to deliver energy from the Índigo Model 830e diode laser only and bears a unique connector for coupling to the 830e at the proximal end.
Modifications have been made to the labeling to clarify use of the fiberoptic. Training and promotional materials have been updated and prepared reflecting these clarifications. None of the changes affects the function, intended use, or overall design of the fiberoptic or of the Índigo LaserOptic® Treatment System.

Intended Use:
The Índigo 830e LaserOptic® Treatment System is intended to be used as surgical instruments used in the non-contact mode to photocoagulate, vaporize/ablate soft tissue (muscle, connective tissue, organ), for cutting, excision, incision, and for coagulation of

soft tissue in the contact mode (open/closed) surgical procedures. When used with bare fiberoptics, the Índigo diode laser can be used for the excision, of external tumors and lesions, complete and partial resection of internal organs, treatment of tumors and lesions, skin incision and tissue dissection and ablation. The Diffuser-Tip Fiberoptic is intended for the safe and effective treatment of Benign Prostatic Hyperplasia (BPH).

Comparison of Technological Characteristics:
The technical and functional characteristics of the Diffuser-Tip Fiberoptic are identical to the existing Diffuser-Tip Fiberoptic.

Nonclinical Tests:
Testing was performed in an *in vitro* porcine model in order to evaluate the effects of fiberoptic penetration depth and angle on temperature changes as measured on a simulated urethral wall. Several different combinations of penetration angles and depths were used and the resulting simulated urethral wall temperatures recorded and compared. The results indicated that while either an increase in penetration depth or angle reduced the temperature increase, the lowest amount of temperature increase resulted from a combination of increased penetration depth and angle.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 6 2001

Ms. Jacquelyn A. Hughes, RAC
Regulatory Affairs Manager
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K003953
Trade Name: Indigo Diffuser-Tip Fiberoptic
with Temperature Sensing Option
Regulatory Class: II
Product Code: GEX
Dated: December 20, 2000
Received: December 21, 2000

Dear Ms. Hughes:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section H. STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known) : K003953

Device Name :

Indigo Diffuser-Tip Fiberoptic with Temperature Sensing Option

Indications for Use :

The Indigo LaserOptic® Treatment System with Diffuser-Tip Fiberoptic is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostates with median and/or lateral lobes ranging in total volume from 20-85cc and for general surgery, general urological and gastroenterological procedures including the incision, excision, and ablation of soft tissues; and coagulative necrosis and interstitial laser coagulation of soft tissues.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-off)
Division of General Restorative Devices

510(k) number K003953

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)